

## REMARKS

This Response is submitted in reply to the non-final Office Action mailed on October 28, 2010. No fees are due herewith this Response. The Director is authorized to charge any fees that may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3712036-00755 on the account statement.

Claims 1-7 are pending in the application. Claims 8-11 and 13-14 were previously withdrawn, and Claim 12 was previously canceled without prejudice or disclaimer. In the Office Action, Claims 1-7 are rejected under 35 U.S.C. §112. Claims 1-7 are also rejected under 35 U.S.C. §103. Applicants respectfully traverse the pending rejections for at least the reasons set forth below.

In the Office Action, Claims 1-7 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Patent Office asserts that "Claim 1 reads 'a liquid product which is water-based and comprises living microorganisms . . . and which is free of carbohydrates that can be metabolized by the microorganisms,'" and states that the limitation is "vague and indefinite because it is not clear what 'microorganisms' and what 'carbohydrates' are being claimed and the boundaries of the patent protection sought is not clear." See, Office Action, page 3, lines 12-17. Applicants respectfully disagree.

The standard for determining whether the definitiveness requirement is met under 35 U.S.C. § 112, second paragraph is "whether those skilled in the art would understand what is claimed when the claim is read in light of the Specification." *Orthokinetics Inc. v. Safety Travel Chairs Inc.*, 1 USPQ 2d 1081-1088 (Fed. Cir. 1986). "If the claims, read in light of the Specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the Courts can demand no more." *North American Vaccine Inc. v American Cyanamid Co.*, 28 USPQ 2d 1333, 1339 (Fed. Cir. 1993). By statute, 35 U.S.C. 112, Congress has placed no limitations on how an applicant claims his invention, so long as the specification concludes with claims which particularly point out and distinctly claim that invention." *In re Pilkington*, 162 USPQ 145, 148 (CCPA 1996).

Applicants respectfully submit that the possible "microorganisms" are clearly identified in the specification. Specifically, microorganisms of the present claims may be, for example, *Lactobacillus*, *Bifidobacterium*, *Streptococcus*, *Lactococcus*, *Enterococcus*, and combinations of same. See, specification, page 8, lines 23-25. As such, Applicants respectfully submit that the "microorganisms" are clearly set forth in the specification. With respect to the carbohydrates that may be metabolized by the microorganisms, the skilled artisan would immediately appreciate that the claim limitation requires that the product is devoid of carbohydrates that may be metabolized by the microorganisms. Specifically, the product does not have a carbohydrate that belongs to the natural carbon source(s) of the microorganisms. The skilled artisan will immediately appreciate which carbohydrates should not be used with which specific microorganisms because each microorganism metabolizes different carbohydrates. The fermentation patterns of each specific microorganism are generally known to the skilled artisan and are readily available in known Molecular Biology reference materials. Thus, the skilled artisan would immediately appreciate which expressly disclosed microorganisms will ferment which carbohydrates. Further, Applicants also respectfully submit that to require Applicants to list each possible strain and every possible carbohydrate that is metabolized by the strain would be unduly burdensome for Applicants.

For at least these reasons, Applicants respectfully submit that Claims 1-7 fully comply with the requirements under 35 U.S.C. §112, second paragraph.

Accordingly, Applicants respectfully request that the rejection of Claims 1-7 under 35 U.S.C. §112, second paragraph, be reconsidered and withdrawn.

In the Office Action, Claims 1-4, 6 and 7 are rejected under 35 U.S.C. §103(a) as being unpatentable over WO 00/53202 to Reniero et al. ("*Reniero*") in view of U.S. Patent No. 7,780,970 to Schlothauer et al. ("*Schlothauer*"). Applicants respectfully submit that the cited references are deficient with respect to the present claims.

Independent Claim 1 recites, in part, liquid products comprising microorganisms, having a shelf-life of at least 1 month at 10°C, during which period at least one characteristic chosen from the group consisting of a pH of the product decreasing less than 2 points and an amount of living microorganisms decreasing less than 2 log-units occurs and which is free of carbohydrates that can be metabolized by the microorganisms. As is described in detail in the specification, the

presently claimed products are shelf-stable because the microorganisms contained therein are able to survive for several months at room temperatures due to their inability to metabolize nutrients contained in the product. See, specification, Abstract. Indeed, the fact that many probiotic bacteria possess an anaerobic metabolism imposes specific technical requirements on all process and product levels between a starting culture and a consumable product suitable to deliver said bacterium in sufficiently high concentration to a human or animal. See, specification, lines 31-34. Further, the mere fact that living bacteria are metabolically active--even at chilled temperatures--imposes problems: ingestible carriers of probiotics often sustain degradation by the bacterial activity, which may render the carrier completely unpalatable. See, specification, page 1, line 36--page 2, line 2.

One way of delivering a probiotic is the preparation of a material, which was fermented by the probiotic. This is the case, for example, with yoghurts that were obtained from fermenting milk with micro-organisms. An advantage of these products is that they are relatively stable when chilled, due to the low pH of the product after fermentation. However, the acid produced by the fermenting activity of the probiotic does not correspond to every consumer's taste. In addition, these products still have to be chilled. See, specification, page 2, lines 21-27. Thus, prior art products having microorganisms may suffer from a number of deficiencies including, for example, the inability to provide a sufficient concentration of the microorganism to the subject, or unpalatability.

In contrast, however, Applicants have surprisingly found that providing microorganisms in a product that does not contain carbohydrates that may be digested by the microorganism results in a product that is shelf-stable for extended periods of time and provides a sufficient amount of microorganisms to the subject. As is further described in the specification, the products according to the present disclosure may be fermented products, which are obtained, for example, by fermenting a medium, heat treating or pasteurizing the medium to reduce bacterial load, and, at the same time, kill the fermenting bacteria. Then the fermented products could be supplemented with a micro-organism, which will not further grow on the fermented medium. For example, the products may be a yoghurt, which is heat-treated and to which micro-organisms which are not able to grow on the fermented, heat-treated product are added, in order to obtain products that fulfill the features of the present claims. See, specification, page 6, lines 20-32. In

contrast, Applicants respectfully submit that the cited references fail to disclose or suggest each and every element of the present claims.

For example, *Reniero* and *Schlothauer* fail to disclose or suggest liquid products comprising microorganisms, having a shelf-life of at least 1 month at 10°C, during which period at least one characteristic chosen from the group consisting of a pH of the product decreasing less than 2 points and an amount of living microorganisms decreasing less than 2 log-units occurs and which is free of carbohydrates that can be metabolized by the microorganism as required, in part, by the present claims. The Patent Office even admits that “*Reniero* et al. do not teach the liquid product (cereal drink) is free of carbohydrates that can be metabolized by the *Lactobacillus*.” See, Office Action, page 6, lines 1-2. Instead, *Reniero* is entirely directed to the prevention of diarrhoea brought about by rotaviruses and pathogenic bacteria. See, *Reniero*, Abstract. Indeed, *Reniero* expressly discloses that the microorganisms (e.g., lactic acid bacterium) used in the compositions must be capable of growing in the presence of bile salts in a composition of up to about 0.4% and may essentially prevent invasion of epithelial cells by rotaviruses. See, *Reniero*, page 3, lines 27-31. *Reniero* refers to liquid products comprising a strain such as *Lactobacillus paracasei* CNCM I-2116, which may be grown, for example, in tomato powder rehydrated with distilled water and used as inoculum.

Tomatoes contain different kinds of carbohydrates. Storage is performed at 10°C for up to 30 days employing a medium comprising 2% wheat flour, 3% rice flour and 3% sucrose, i.e., a medium containing different kinds of carbohydrates in high amounts. *Reniero* clearly discloses storage of such a liquid product with added carbohydrates only. It is neither disclosed nor suggested that long term storage at high temperatures of a liquid product containing said strain may be performed in case metabolized carbohydrates are omitted. As such, it is clear that *Reniero* merely discloses that “Lactic acid bacteria are utilized as fermenting agents for the preservation of food taking benefit of a low pH and the action of fermentation products generated during the fermentative activity thereof to inhibit the growth of spoilage bacteria. To this end, lactic acid bacteria have been used for preparing a variety of different foodstuff such as cheese, yogurt and other fermented dairy products from milk.” See, *Reniero*, page 1, lines 17-21. *Reniero* fails to disclose or suggest producing liquid milk-based products containing

probiotics that may be stored for 1 month at 20°C, wherein at the same time pH and amount of living bacteria decreases less than a factor of 100, as is required, in part, by the present claims.

*Schlothauer* is entirely directed to sucrose free products that have a reduced detrimental effect on the teeth. See, *Schlothauer*, column 11, lines 29-30. However, in contrast to the characterization of *Schlothauer* by the Patent Office, *Schlothauer* discloses a composition comprising a viable lactic acid bacterium ("LAB"), an enzyme synthesized by said lactic acid bacterium and an EPS produced by said enzyme. The product is formed in situ by cultivating the lactic acid micro-organism with a suitable enzyme substrate. A suitable enzyme substrate can be any sugar molecule such as monosaccharides, di-, tri- or tetrasaccharides. By way of a non-limiting example, monosaccharides include sugars such as glucose, fructose or galactose while disaccharides include sugars such as maltose, lactose or sucrose. Other sugar molecules that can be used as a suitable enzyme substrate include the galactoside sugar molecules such as raffinose, stachyose, or verbascose. See, *Schlothauer*, column 4, lines 5-19; columns 11-12. As such, *Schlothauer* fails to remedy the deficiencies of *Reniero* and does not help *Reniero* solve the problem of providing a shelf-stable liquid product containing probiotics with poor viability loss.

At no place in the disclosures do either *Reniero* or *Schlothauer* disclose or suggest liquid products comprising microorganisms, having a shelf-life of at least 1 month at 10°C, during which period at least one characteristic chosen from the group consisting of a pH of the product decreasing less than 2 points and an amount of living microorganisms decreasing less than 2 log-units occurs and which is free of carbohydrates that can be metabolized by the microorganism as required, in part, by the present claims.

The Patent Office asserts that *Reniero* discloses lactose and a microorganism that does not metabolize lactose (e.g., *L. casei* CNM I-2116). See, Office Action, page 5, lines 16-18. Along the same lines, however, Applicants respectfully submit that the Patent Office cannot ignore certain portions of *Reniero* that disclose the use of microorganisms in combination with carbohydrates that may be metabolized by those microorganisms. For example, in addition to *L. casei*, *Reniero* also discloses the use of yeast and tryptose phosphate broth. See, *Reniero*, page 10, line 31-page 11, line 6. Tryptose phosphate broth is a versatile nutritionally rich buffered glucose broth. Further, the skilled artisan would immediately appreciate that glucose is

metabolized by both lactose and yeast. As such, Applicants respectfully submit that *Reniero* is not free from any carbohydrates that may be metabolized by the microorganisms.

Further, *Reniero* expressly discloses in Figure 2 the acidification of *L. casei* ST11 in growth media wherein the amount of living microorganisms decreases by more than 2 log-units. Indeed, each of the curves in Figure 2 demonstrates a starting point of 6.5 and an ending point of 4.5 or lower. See, *Reniero*, Figure 2. This is in direct contrast to the present claims, which require, in part, liquid products comprising microorganisms, having a shelf-life of at least 1 month at 10°C, during which period at least one characteristic chosen from the group consisting of a pH of the product decreasing less than 2 points and an amount of living microorganisms decreasing less than 2 log-units occurs.

For at least the reasons discussed above, Applicants respectfully submit that Claims 1-4 and 6-7 are novel, nonobvious and distinguishable from the cited reference.

Accordingly, Applicants respectfully request that the obviousness rejection of Claims 1-4 and 6-7 under 35 U.S.C. §103 be reconsidered and withdrawn.

In the Office Action, Claims 1- 7 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Reniero* in view of Current Issue Intest. Microbila., 2002, Vol. 3, p. 39-48 to Kailasapathy (“*Kailasapathy*”) and further in view of U.S. Patent No. 5,382,438 to Hottinger et al. (“*Hottinger*”). Applicants respectfully submit that the cited references are deficient with respect to the present claims.

As discussed above, independent Claim 1 recites, in part, liquid products comprising microorganisms, having a shelf-life of at least 1 month at 10°C, during which period at least one characteristic chosen from the group consisting of a pH of the product decreasing less than 2 points and an amount of living microorganisms decreasing less than 2 log-units occurs and which is free of carbohydrates that can be metabolized by the microorganisms. As is further discussed above, *Reniero* fails to disclose or suggest each and every element of the present claims, as is admitted by the Patent Office. Because the Patent Office admits that *Reniero* fails to disclose or suggest each and every element of the present claims, see, Office Action, page 6, lines 1-2, the Patent Office cites *Kailasapathy* and *Hottinger*. Applicants respectfully submit that *Kailasapathy* and *Hottinger* fail to remedy the deficiencies of *Reniero* because *Kailasapathy* and *Hottinger* also fail to disclose or suggest each and every element of the present claims. As such,

Applicants respectfully request that the Patent Office reconsider and withdraw the pending rejections.

For example, *Kailasapathy* and *Hottinger* fail to disclose or suggest liquid products comprising microorganisms, having a shelf-life of at least 1 month at 10°C, during which period at least one characteristic chosen from the group consisting of a pH of the product decreasing less than 2 points and an amount of living microorganisms decreasing less than 2 log-units occurs and which is free of carbohydrates that can be metabolized by the microorganism as required, in part, by the present claims. Instead, *Kailasapathy* is not even directed to analogous subject matter since *Kailasapathy* is directed entirely to encapsulation and immobilization of microorganisms to solve the problem of viability by encapsulating probiotics. Despite the fact that *Kailasapathy* discloses microorganisms, *Kailasapathy* is not related to present claims in any other manner. Indeed, the skilled artisan would not look to *Kailasapathy* to remedy *Reniero* to arrive at the present claims merely because *Kailasapathy* mentions microorganisms. Applicants submit that such a combination is extremely attenuated and improper since *Kailasapathy* is not analogous art.

*Hottinger* is entirely directed to yogurt that is prepared by inoculating and fermenting a milk with a symbiotic combination of both *S. thermophilus* and *L. bulgaricus*. See, *Hottinger*, Abstract. However, *Hottinger* expressly disclose that “the ‘L. bulgaricus’ mutant is apparently incapable on its own of fermenting lactose although, cultured in a milk in symbiosis with ‘S. thermophilus’, it is capable of acidifying this milk almost as well as the mother strain from which it has come.” See, *Hottinger*, column 3, lines 9-17. As such, Applicants respectfully submit that the entire invention of *Hottinger* is directed to the use of *S. thermophilus* and *L. bulgaricus* in symbiosis to ferment a carbohydrate. This is in direct contrast to the present claims, which require the products to be free of carbohydrates that may be fermented by a microorganism.

For at least the reasons discussed above, Applicants respectfully submit that Claims 1-7 are novel, nonobvious and distinguishable from the cited reference.

Accordingly, Applicants respectfully request that the rejection of Claims 1-7 under 35 U.S.C. §103 be reconsidered and withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly request an early allowance of the same. In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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